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K002364

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IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ESPE Dental AG

Street: ESPE Platz

ZIP-Code, City: D-82229 Seefeld

Federal State: Bavaria

Country: Germany

Establishment Registration Number: 9611385

Contact: Dr. Andreas Petermann
Manager U.S. Regulatory Affairs

Phone: 01149-8152-700 1395

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E-mail: Andreas.Petermann@ESPE.de

Date of Submission: July 31, 2000

Name of Device

Proprietary Name: Protemp® H

Classification Name: Temporary Crown and Bridge Resin

Common Name: Composite based Temporary Crown and Bridge Material

Predicate Device:

Protemp® Garant® K 950203

Description for the Premarket Notification

Protemp® H is a temporary crown and bridge resin intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated. Temporary crown and bridge resin is designated at 21 C.F.R § 872.3770 as a Class II device.

ESPE is submitting this Special 510(k) for modifications to its composite based temporary crown and bridge material Protemp® Garant®.

Like Protemp® Garant®, Protemp® H is available in the proven Garant® mixing and dispensing system.

The modified temporary crown and bridge material Protemp® H has the following similarities to the unmodified Protemp® Garant®:

- Protemp® H has the same intended use.
- Protemp® H is used by the same operating principle.
- Protemp® H incorporates the same basic chemical design.
- Protemp® H has the same shelf life.
- Protemp® H is manufactured and packaged using the same materials and processes.

Protemp® H contains one ingredient which is not contained in known predicate devices. To provide evidence for safety, biocompatibility testing was carried out by an independent research institute. The results show that Protemp® H is a safe device.

In summary, the modified material Protemp® H described in this Special 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Andreas Petermann
Manager U.S. Regulatory Affairs
ESPE Dental AG
ESPE Platz
Seefeld, Bavaria,
GERMANY

Re: K002364
Trade Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: July 31, 2000
Received: August 3, 2000

Dear Mr.Petermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002364

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K002364

Device Name: Protemp® H

Indications for use: Fabrication of Temporary Crowns and Bridges, Inlays and Onlays

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002364

Prescription use: ☑ Over-the counter use ☐